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ABSTRACT

As part of the evaluation of four different versions of a patient package insert (PPI) for diazepam (Valium) created by the Food and Drug Administration (FDA), the content, organization, language, and design of the PPIs were compared. One PPI was a short prose piece with clear organization that did not particularly highlight warnings or, indeed, any specific piece of information. The second PPI was clear, personal in tone, and had a high level of explanation. It also stressed warnings more than the other versions by placing this section first, by highlighting it with use of large type and a box, and by using the word "warnings" rather than "cautions." The third PPI had a more complex style and organization than the first two PPIs, with a higher level of personalism but not as high a level of explanation as the fourth PPI. The last version of the PPI had the most difficult language style and the most complex graphic design. It did not use a personal tone but it had a high level of information and explanation. (RL)

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DOCUMENT DESIGN PROJECT

Technical Assistance Report No.1

Differences in the Language and Design of Four PPIs for Valium

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Prepared for: Prescription Drug Labeling Staff, Bureau of Drugs, Food and Drug Administration, Washington, D.C.

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OCT 2 0 1980

Differences in the Language and Design of Four PPIs for Valium

The Prescription Drug Labeling Staff at the Bureau of Drugs, Food and Drug Administration (FDA) recently created four different versions of a patient package insert (PPI) for diazepam, i.e. Valium. The four PPIs were then tested in focused group interviews by an outside firm to see which documents were easier for consumers to understand and which consumers preferred. At the same time, the FDA asked the Document Design Project (DDP) to analyze the four PPIs so that differences in consumers' comprehension and attitudes could be linked to differences in the documents.

The analysis reported in this paper is entirely post hoc. AIR was not involved at the design stage; and DDP staff have not met with the people who wrote the PPIs to find out what guidelines they were following. It is not wise to try to infer after the fact what was in the minds of writers when they were doing their work. Therefore, we can only describe how the four PPIs differ along a series of dimensions that might be relevant to consumers' understanding and attitudes.

We looked at differences in content, organization, language, and design. (We did not run readability formulas on the PPIs because the FDA had already done that.) Dr. Janice C. Redish did the analysis and wrote the report with the help of Virginia Sheard (on format) and Dr. Robert E. Krug (information in table #1).

The results of our analysis are laid out on the following pages. For convenience we have numbered the four versions as follows:

1 is the shortest version (2 sides)

2 is the one with 2 folds that starts off with IMPORTANT WARNINGS

3 is the smaller of the 1-fold, 4-sided versions

4 is the extra tall version that starts with the name VALIUM in large letters

The four PPIs are appended to this report.

Content

Each of the PPIs covers certain basic facts about uses, cautions and side effects. But the lists of warnings and of side effects are not identical. Furthermore, each version gives at least some additional information that is missing in one or more of the others. The chart on the next two pages allows a comparison of the facts covered by the four PPIs.

Glancing at the chart, for example, we can see that only the fourth PPI gives prominence to the common name, valium. The third and fourth PPIs don't describe the three colors the pills come in at all. Only the fourth gives information about how much to take although the wording even there is not very specific. Two of the PPIs (numbers 1 and 3) include a warning about not taking a double dose when one is missed. The other two PPIs are silent on this topic.

It is interesting that all four give the same uses although all but the fourth add a little more information. In the long column on side effects, we see that PPI #2 lists many more than any of the others. PPI #2 also includes more "other information" than any of the others. There is progressively more information about what not to take if you are taking valium as we go from PPI 1 to 3. In summary, the charts show that there are content differences among the four PPIs.

Content			PPI Number 1	2	3	4
NAMES	gives DIAZEPAM as name of drug		●[1]	●	●	●[1]
	gives prominence to name DIAZEPAM over any other		●	●	●	
	gives equal prominence to name VALIUM					●
	calls drug DIAZEPAM throughout PPI		●	●	●	
	mentions VALIUM as trade/brand name		●	●	●	●
	mentions class name (benzodiazepine)			●	●	●[1]
	mentions functional name (minor tranquilizer)					●
DESCRIPTION	three strengths		●	●		
	also injection			●		
DOSAGE	information about specific dosages					●
	statement about importance of correct dosage		●	●	●	
	caution—"if you skip a dose, do not take extra"		●		●	
USES	anxiety and tension		●	●	●	●
	relax muscles		●	●	●	●
	alcohol withdrawal		●	●	●	●
	epileptic seizures		●	●	●	●
	also mentions:	serves as a tranquilizer	●			
		nerve pill		●		
		sleeping difficulties associated with tension			●	
MENTIONS LENGTH OF TIME TO WORK			●		●[2]	
MENTIONS HOW IT WORKS				●		●
SIDE EFFECTS	drowziness		●	●[3]	●[4]	●[3]
	dizziness		●	●	●[4]	●
	confusion		●	●		
	fainting				●[4]	●
	weakness		●			
	fatigue			●[3]	●[4]	●[3]
	trouble urinating			●	●	●
	impaired bladder control		●	●	●	●
	constipation		●	●	●[4]	●
	skin rash		●	●	●[4]	●
	yellowing of skin/eyes		●	●	●	●
	inability to sleep		●	●	●	●
	getting angry or excited		●	●	●	●
	depression			●	●	
	blurred vision			●	●[4]	
	loss of muscle coordination			●[3]	●[4]	●[3]
	eye pain				●	●
	headaches			●	●	
	low blood pressure			●		●
	inability to speak clearly			●		
	changes in sex drive			●		
	nausea			●		
	tremors			●		
	fever and sore throat				●	

Figure 1. Content Analysis of Four PPIs

Figure 1. continued

Content			PPI Number 1	2	3	4
USE OF WORD "CAUTION"			●		●	●
USE OF WORD "WARNING"				●		
CAUTIONS/ WARNINGS	pregnancy		●	●[5]	●	●[5]
	allergy		●	●	●	●[5]
	glaucoma		●	●	●	●[5]
	liver problems		●	●		●[5]
	epileptic seizures		●		●	
	kidney problems			●		●[5]
DON'T MIX WITH . . .	alcohol		●	●	●	●
	sleeping pills		●	●	●	●
	other tranquilizers		●	●	●	●
	anti-depressants			●	●	●
	narcotics				●	●
	certain cold and cough medicines				●	●
	antihistamines				●	●
DON'T GIVE TO CHILDREN UNDER SIX MONTHS			●	●	●	●[5]
CAUTION ABOUT DRIVING, etc.			●	●	●	●
OTHER INFORMATION	information about dependence:	very little	●	●		
		a lot			●	●
	information about overdose:	little	●	●		
		describes symptoms			●	●
		what to do			●	●
	effectiveness of more than four months not proved			●	●	
	check with your doctor every four months		●	●	●	
	for more information ask your doctor or pharmacist			●	●	
	how many refills			●		
	doctor may order blood tests			●	●	●
	if you have an electroencephalogram . . .			●		

1 = includes pronunciation
2 = detailed explanation given
3 = listed as common
4 = strung out in prose narrative; others are bulleted as "serious, but rare"
5 = includes explanation

Organization

The short version has the clearest organization:

NAME + DESCRIPTION

USES

SIDE EFFECTS

CAUTIONS

Each of the others elaborates on this structure. The second version stresses WARNINGS even before uses or description. The third and fourth have eleven sections each giving some cautions before listing side effects and more cautions at the end. Here are the four structures next to each other for comparison:

	PPI 1	PPI 2	PPI 3	PPI 4
1.	names and descriptions	names	names	names
2.	uses	warnings	uses	uses
3.	side effects	uses	dosage	how it works
4.	cautions	how it works	general cautions	general cautions
5.		description	cautions	cautions
6.		side effects	cautions about activities	other drugs
7.		other information	other drugs	common side effects
8.			common side effects	less frequent side effects
9.			serious but rare side effects	dosage
10.			overdosage	overdose
11.			effects of long term use	effects of long term use
			(3-7 and 10-11 are all warnings)	(4-6 and 10-11 are all warnings)

The organization of three and four may be more difficult for readers to follow than that of one or two because they have so many sections and because cautions are given in different places. The stress on warnings in the organization of two may have an impact on patients' recall and attitudes.

Language

In this section we briefly point out the strengths and weaknesses of the style used in each version.

PPI 1. The short version is written in prose paragraphs and in complete sentences. Most of the sentences are active and declarative, but some are complex. Many of the sentences are abstract and impersonal. They begin with phrases such as: There are . . .; It is important . . .; It usually takes . . .; There may be . . . To appreciate the impersonal tone, compare these two sentences: version 1, "It usually takes about an hour after swallowing the drug to feel its relaxing effect." version 3, "Some patients feel better within an hour after first taking the drug." This sentence from version 3 gives a much more direct personal message than the first one does.

The average sentence length in version 1 is 14.25 words. While this is not a terribly high figure, several of the sentences contain lengthy lists that may be difficult for the reader to follow or remember. The same information appears in the other versions as bulleted or numbered listings. Did consumers recall side effects better from the other versions than they did from this prose description?

Technical words occur in version 1 without explanation: glaucoma, anxiety, tranquilizer, impaired bladder control. A lay definition is given for epileptic seizures the first time it is used but not the second. On the other hand, because this version is quite short, there is not an overwhelming feeling of technical jargon.

In summary, the writer has chosen brevity over depth of explanation and has chosen not to use graphic techniques for emphasizing any particular item of information.

PPI 2. The second version is a mixture of lists and very short paragraphs. Many of the sentences are imperatives (do this, do not do that, call your doctor . . .). In a comparison of versions 1 and 2, we would expect patients to recall cautions better from #2 because of the imperative construction, the tone of warning, and the spacing out of the different cautions in a numbered list.

The heavy use of the pronoun "you" also imparts a tone of speaking directly and personally to the patient. There is very little use of undefined technical vocabulary -- definitions in parenthesis are common.

In general, the language of this version is very clear. Each item in the list of warnings is a complete sentence. In the other lists, the items are parallel constructions, always equivalent predicates to the subject-verb construction in italics above the list. In each case, the introduction plus the list forms a complete active declarative sentence. This should make the lists in #2 easier to read and remember than those in #3 and #4.

There are two interesting questions related to the use of numbered lists. First, do people remember more items from a numbered list than they do from a bulleted (unnumbered) list? That is, does knowing how many items there are aid in remembering the list? Secondly, do people think that items in a numbered list are given in rank order while items in a bulleted list are all equal in importance? Do people who are given a numbered list remember the first few items best while people who are given a bulleted list recall items scattered throughout the list? It would be interesting to know if the comprehension tests used in the group interviews shed light on these questions.

PPI 3. This version combines text in lengthy paragraphs with bulleted lists. The text is a mixture of imperatives and sentences with explanatory information. Some of the explanatory sentences are lengthy and include strings of prepositional phrases which make reading difficult. The items in the list under general cautions are all agents of a passive sentence. The other two lists are introduced by long explanations. It would be interesting to know how well these are recalled compared to the contextual lists in version 2.

In this third version, the common side effects are strung out in a prose sentence while the serious side effects are listed. It would be interesting to know if the list facilitates recall; but in this particular case, it would be difficult to know if better recall of the second group of side effects is due to the way they are presented or to the fact that they are labelled as "serious".

PPI 4. The language of the fourth version will probably be most difficult for the readers. This PPI consists mostly of bulleted lists. Many sections include non-sentences, for example, "USES treatment of: • anxiety. . ." The section on EFFECTS OF LONG TERM USE on the last page includes a mixture of non-sentences presented as if they were sentences (with initial caps and period) and one real sentence. Some of the sentences are very long. The items in the list under GENERAL CAUTIONS are all agents of a passive sentence (as in version 3) with the added complication that each item is quite long because it includes an explanation. The entire section is one sentence that is 119 words long.

This version is not personal. The pronoun "you" is not used at all. The grammar is also quite stilted and complex. Most sentences are in the passive. Where version 3 says "If any of the above apply, <u>you should immediately tell your doctor</u>",

version 4 says, "If . . . , the prescribing physician should be informed before taking the drug." This sentence has, in fact, three problems: (1) It uses the technical term "prescribing physician" for "doctor". (2) It is in the passive ("should be informed") and the agent ("by whom") is not mentioned. Research shows that agentless passives are even more difficult for readers than passives with the agent expressed. (3) It has a dangling participle -- who will be taking the drug? the doctor?

In several places the fourth PPI uses the passive where the others have a direct imperative. "The doctor should be consulted" instead of "Consult your doctor". In the last section, all three items are in the passive including the very awkward phrase "signs of dependency should be watched for."

While the level of explanation is very high in this version, in order to understand the explanation the reader must have a sophisticated vocabulary. Technical terms such as "limbic system", "liver disorder", "epileptic seizure" are not defined. We would predict that the fourth version is difficult for readers to understand and remember because of the complexity and impersonal nature of the language and the problems mentioned under "format" (use of many type fonts, white space used evenly rather than to separate sections).

Summary of organization and language features

The following table summarizes some important factors about the organization and language of the four PPIs.

Table 1. A Summary Comparison of Four PPIs for Valium

PPI No.	Words text	Words heads	Words total	Length	Sections	Description	% Prose	Definitions	Personal "you, yours"	Personal "imperative"	Personal total
1.	285	77	292	1	4	straight prose	1.0	3	12	2	14
2.	724	22	746	2.55	7	numbers + prose	.38	18	23	13	36
3.	635	27	662	2.27	11	mostly prose, some bullets	.72	6	18	13	31
4.	551	37	588	2.01	11	mostly bullets, some prose	.11	14	0	4	4

The first three columns show the number of words used (text, headings and total). In the fourth column we show the relative length (in words - not physical size) of each version. Taking the short version as the standard, we see that the fourth is twice as long and the second is the longest.

Column five shows the number of sections into which each PPI is divided. You can see that while the third and fourth versions are shorter than the second, they are broken into many more sections. The description in column six indicates the different combinations of prose and lists; a quantitative measure of this combination is given in the following column. This seventh column shows that a major difference between versions 3 and 4 is the use of long prose segments in #3 compared to the use of non-prose lists in #4.

The eighth column is an indication of the level of explanation in each of the PPIs. We counted as definitions each explanation or definition included in parentheses. Other explanations may occur in the text. Therefore, these figures should not be taken as absolute values for the number of explanations, but rather as relative indicators. As such, this column shows clearly that versions 2 and 4 provide much more in the way of explanations to readers than either version 1 or version 3.

The last set of columns uses two indicators to show relative degrees of "personalism". The first figure is the number of times the second person pronouns "you" and "your" are used. The second figure is the number of imperative sentences (do not take . . ., tell your doctor . . .). These figures show that versions 2 and 3 take a much more direct personal approach to the patient than either 1 or 4 and that 4 is the least personal of this set of PPIs.

Design

Table 2 below summarizes some of the major differences in the format, typography and general layout of the four PPIs. They differ not only in physical size, but in the number of sizes and variations of typeface and in the use of lists vs. narrative. The overall impression one gets from the first (short) PPI is of straight information with nothing in particular emphasized by graphic techniques. The fourth PPI is not only physically largest, but uses so many typographical variations that it may confuse the reader. The use of variation and white space in

the second and third PPIs should help the reader follow the organization and understand which sections the writer meant to emphasize.

Table 2. Graphic Features of the Four PPIs

	PPI 1	PPI 2	PPI 3	PPI 4
FORMAT				
page size (per side)	3-11/16" x 7-15/16"	3-7/16" x 6-3/16"	3-7/16" x 7-15/16"	3-15/16" x 10-7/16"
number of folds	none	2	1	1
number of sides printed	2	2	2	2
TYPOGRAPHY				
number of different faces	3	2	1	1
variations with faces (italics, bold, light, etc.)	1	2	3	5
number of sizes	3	4	3	3
DESIGN				
number of head sizes	1	2	2	4
numbered items	no	yes	no	no
bulleted items	no	no	yes	yes
boxed elements	no	yes	no	yes
general format	narrative format does not emphasize or categorize copy by variations in type size trade off of compact length for lack of white space consistent size and face of type does not put more emphasis on any one part of content	combined outline and narrative with bold heads and more white space between copy blocks aids organization use of numbers may imply rank order and be misleading	combined narrative and itemized listing use of extra white space between copy blocks aids organization probably most effective visual organization	itemized listing of copy in outline form equal white space between copy lines and copy blocks looses sense of organization no descriptive narrative preceeding listings of features monotony of type style and face/size does not indicate relative importance of pieces of copy

Conclusion

The preceding description compares the content, organization, language and design of four versions of a PPI for Valium. One is a very short prose piece with clear organization that does not particularly highlight warnings or indeed any specific piece of information. The second is clear, personal in tone and has a high level of explanation. It also stresses warnings more than the others by placing this section first, by highlighting it with use of large type and a box and by using the word "warnings" rather than "cautions." The third has a more complex style and organization than the first two, a higher level of personalism but not as high a level of explanation as the fourth. The last version has the most difficult language style and the most complex graphic design. It does not use a personal tone but it has a high level of information and explanation. We would be very interested in knowing if any correlations can be drawn between the features of each PPI that we have described and the data on consumers' comprehension and preference from the focused group interviews.

APPENDIX: Four PPIs for Diazepam (Valium)

PPI No. 1

Front

DIAZEPAM

The drug prescribed for you is diazepam (die-AZE-a-pam). It is sold under the name of Valium. There are three different strengths available. The 2mg (milligram) tablet is white, the 5mg tablet is yellow, and the 10mg tablet is blue. It is important to understand the dose you are taking and when you should take it, so that you can get the best results.

WHAT IS DIAZEPAM FOR?

Diazepam is used to relieve anxiety and serves as a tranquilizer. It is also used to help relax muscles, to treat alcohol withdrawal and epileptic seizures (fits). It usually takes about an hour after swallowing the drug to feel its relaxing effects.

SIDE EFFECTS

Diazepam can cause drowsiness or dizziness. Its effects may be dangerous when operating machinery, driving or other activities where you must be alert. For some persons, there may be more serious side effects. For example, there may be confusion, weakness, impaired bladder control or constipation. Also, there may be skin rash, yellowing of the skin or eyes or inability to sleep, or getting angry or excited easily.

Back

CAUTIONS

Make sure your doctor knows if you are pregnant; if you have had any allergic reaction to diazepam or another tranquilizer, or if you have glaucoma or liver problems or have had epileptic seizures. These conditions can lead to serious drug reactions.

Diazepam can cause physical and mental dependence if taken in large doses over a long period of time. You should check with your doctor every four months to see if you still need to take diazepam.

While taking diazepam, you should be very careful drinking alcohol, taking sleeping pills or other tranquilizers. Diazepam is not usually prescribed for small children (under six months). If an overdose occurs, get emergency help right away.

DIAZEPAM

Actual size (trimmed): 3-3/4" x 7-15/16"

PPI No. 2

(outside)

fold

7 Low blood pressure (feeling dizzy or faint when you stand up suddenly)

8 Trouble urinating (passing water) or controlling when you urinate

9 Jaundice (a yellowing of the skin or the whites of the eyes)

10 Changes in sex drive

11 Nausea (feeling sick to the stomach)

12 Changes in salivation (the amount of water in the mouth)

13 Tremors (shaking of the body, especially the hands)

14 Dizziness

15 Reactions such as getting excited or angry easily, trouble sleeping, or having hallucinations.

16 Skin rash

Should any of these side effects occur, call your doctor immediately. You should not suddenly stop taking diazepam without talking to your doctor, especially if you have been taking it for a long time or for convulsions.

OTHER INFORMATION

If you forget to take a dose, do not take an extra tablet the next time.

Use of diazepam for longer than four months has not been proven effective. Your doctor should review your need for the drug every four months.

Your doctor may ask you to have blood tests done periodically.

If you have an electroencephalogram (a brain wave test), tell your doctor that you are taking diazepam.

If your doctor approves, the prescription may be refilled up to five times within the next six months. Further refills are not allowed. Your doctor needs to give you a new prescription.

If you want more information about diazepam, ask your doctor or pharmacist to see a copy of the technical labeling written for them.

If you have any questions about diazepam or the information in the leaflet, ask your pharmacist or doctor.

fold

DIAZEPAM

The drug prescribed for you is diazepam. It's trade name is Valium and it is one of the class of drugs known as benzodiazepines.

It is important that you read and understand the information in this leaflet. If you have any questions, ask your pharmacist (druggist) or doctor.

IMPORTANT WARNINGS

1 Since diazepam can make you feel sleepy and less alert, be careful driving or doing other things that require alertness, at least until you have taken the drug for a few days. Know how the drug affects you.

2 Do not drink alcohol while taking diazepam.

3 Do not take other drugs for anxiety, depression, pain, or to help you sleep unless your doctor knows you are also taking diazepam.

(inside)

IMPORTANT WARNINGS

4 Do not take diazepam if you ever had an allergic reaction to it or other similar drugs such as Librium, Daimane, Serax, Tranxene, Ativan, or Verstran.

5 Do not take diazepam if you are pregnant, since it may cause birth defects, especially if taken during the first three months of pregnancy.

6 If taken in large dosages for long periods, diazepam may cause dependence or addiction (which can cause serious withdrawal symptoms if you stop taking it.)

7 If you have a liver or kidney problem, tell your doctor before you start taking diazepam.

8 Do not take diazepam if you have an eye condition known as acute narrow angle glaucoma.

9 Do not give diazepam to children less than six months old.

10 Do not take more than your doctor has prescribed. If an overdose has been taken, get emergency treatment.

fold

WHAT DIAZEPAM IS USED FOR

Diazepam is used:

1 To help relieve tension or anxiety (as a "nerve pill")

2 To help you with acute alcohol withdrawal

3 To help relieve muscle spasms

4 Along with other drugs to help prevent convulsions or fits (such as those caused by epilepsy).

HOW DIAZEPAM WORKS

It is not known exactly how diazepam works. It is thought that diazepam acts on the parts of the brain that control emotions (the limbic system).

WHAT DIAZEPAM LOOKS LIKE

Diazepam comes in a 2 milligram strength (white tablet), 5 milligram strength (yellow tablet) and 10 milligram strength (light blue tablet). It can also be given as an injection.

SIDE EFFECTS OF DIAZEPAM

Side effects are generally unwanted results of taking a drug. All drugs may cause side effects.

fold

Not every person has side effects when taking a drug. Many people have no unpleasant effects, or just a few.

Side effects common to diazepam are:

1 Drowsiness

2 Fatigue (feeling "tired" during the day)

3 Loss of muscle coordination (especially the ability to walk straight or without stumbling).

If any of these becomes severe or troublesome, call your doctor for advice as soon as possible.

Infrequent but serious side effects of diazepam include:

1 Confusion (an inability to think clearly)

2 Constipation (difficult, incomplete or infrequent bowel movements)

3 Depression (a feeling of sadness)

4 Double or blurred vision

5 Stammering, stuttering or an inability to speak clearly

6 Headaches

Actual size (trimmed and folded): 3-7/16" x 6-3/16"

PPI No. 3

(outside)

fold

EFFECTS OF LONG TERM USE

The effectiveness of Diazepam in long term use (more than four months) has not been established. The following special problems may arise if large excessive doses of the drug are used over an extended period of time:

- Possible dependance (an inability to function normally without the drug)
- Greater risk of serious side effects
- Withdrawal symptoms such as depression, stomach cramps, vomiting, and tremor, if the drug is stopped abruptly

You can guard against these risks by watching for signs of dependence. Consult with your doctor at least every 4 months about the continued need for treatment. Your doctor may need to take periodic blood tests. Do not abruptly stop taking the drug without consulting your doctor.

DIAZEPAM

The name of this drug is diazepam. Its brand name is Valium and it is a member of a class of drugs called benzodiazepines.

USES AND BENEFITS

Diazepam is mainly used for anxiety and nervous tension, sleeping difficulties associated with anxiety, and muscle stiffness or spasm. It is also used to reduce symptoms of alcohol withdrawal and to help control epileptic seizures (fits). Some patients feel better within an hour after first taking the drug, but others may need several days of regular use of the medication before noticing beneficial effects.

DOSAGE

It is important to take this drug exactly as prescribed by your physician. Read the label on the box or bottle carefully to be sure the directions are clear. Ask your doctor or pharmacist to explain any part of the instructions that you do not understand. If you miss a dose of the drug, do not take twice as much the next time.

(inside)

fold

GENERAL CAUTIONS

This drug should NOT be used by:

- Women in the first 3 months of pregnancy
- Infants under 6 months of age
- Persons who have had allergic reactions to this drug.
- Persons who have narrow angle glaucoma (an eye disease)

If any of the above apply, you should immediately tell your doctor.

CAUTIONS

Before taking this drug, be sure your doctor knows if you have (1) epilepsy, or (2) open-angle glaucoma.

CAUTIONS ABOUT REGULAR ACTIVITIES

Take great care when driving or operating dangerous machinery until the effects of the drug are known. The drug may make you drowsy, less alert mentally, or impair muscle coordination. Be very careful about drinking alcohol while on the drug. This combination may lead to unexpected increases in the effects of both the alcohol and the drug even if the two are taken within 24 hours of one another.

OTHER DRUGS

To avoid possible medical problems, make sure your doctor knows if you are taking any prescription or nonprescription drug. The effects of diazepam may be increased by other drugs such as antihistamines, sleep aids, cough and cold remedies, alcohol, other tranquilizers, antidepressants or narcotics.

COMMON SIDE EFFECTS

When you first start taking this drug you may feel tired drowsy unsteady or notice other difficulties in muscle coordination. These side effects should not last for more than a few days; if they last for more than 5 days contact your doctor. Occasionally, this drug may cause skin rash, blurred or double vision, dizziness or fainting, or constipation. If you notice any of these reactions, be sure to tell your doctor as soon as possible.

SERIOUS BUT RARE SIDE EFFECTS

This drug may infrequently cause some more serious side effects. You can help prevent major problems by being aware of the following danger signals:

- Eye pain or headaches near the eyes
- Difficulty urinating or poor bladder control
- Yellowing of the skin or eyeballs
- Fever and sore throat
- Great excitement, increased anxiety and inability to sleep (called paradoxical reactions because they are the opposite of what would be expected)
- Emotional depression

If any of the above symptoms occur, notify your doctor immediately.

OVERDOSAGE

An overdose is likely to exaggerate the drug's normal effects, causing extreme drowsiness, weakness, feeling of drunkeness, staggering and shakiness. Overdosage could lead to coma (unconsciousness).

Get emergency help immediately.

Actual size (trimmed and folded): 3-7/16" x 7-15/16"

20

PPI No. 4

Front

OVERDOSE

Effects of an overdose:

- marked drowsiness
- weakness
- feeling of drunkenness
- staggering
- shakiness
- coma or unconsciousness

Get emergency help immediately.

EFFECTS OF LONG TERM USE

Possible dependence, an inability to function normally without the drug.

Withdrawal symptoms such as depression, stomach cramps, vomiting, and tremor, if the drug is stopped.

Greater likelihood of experiencing adverse reactions.

The effectiveness of diazepam in long term use (more than four months) has not been established.

To guard against these risks:

- signs of dependency should be watched for
- the drug should not be stopped abruptly (gradual lowering of the dose reduces the chances of withdrawal symptoms)
- regular liver and blood tests may need to be taken (this will give early warning of adverse reactions)

fold

TRADE NAME

VALIUM

(Val-E-um)

GENERIC NAME

DIAZEPAM

(die AZE-a-pam)

CLASS

BENZODIAZEPINE

(ben-zoe-die-AZE-a-peen)

FUNCTIONAL NAME

MINOR TRANQUILIZER

(anti-anxiety drug)

USES

Treatment of:

- anxiety and tension
- muscle stiffness and spasm
- symptoms of alcohol withdrawal
- control of epileptic seizures

ACTION

- General emotional and physical calming effect (by its action on the emotional centers in the brain – limbic system, thalamus and hypothalamus).
- muscle relaxation

GENERAL CAUTIONS

This drug should not, generally be used by:

- women in the first three months of pregnancy, as the baby's development might be affected.

Back

- people who have glaucoma (narrow angle type) as the drug can lead to further increased pressure inside the eyeball.
- infants under six months of age, because it is not known if the drug is safe for children of this age.
- people who have had allergic reactions to this or similar drugs because the body is sensitized and further allergic reactions may occur, sometimes in much more serious form.
- people who have kidney or liver diseases, these people may need to have their dose adjusted, because their body will be less efficient in dealing with the drug.

If any of the above apply, the prescribing physician should be informed before taking the drug.

CAUTIONS ABOUT YOUR REGULAR ACTIVITIES

Take great care when driving or operating machinery until the effects of the drug are known. (It might cause drowsiness or produce muscle coordination problems.)

Avoid drinking alcohol while taking the drug. (Alcohol and diazepam may have additive effects and increase the severity of side effects.)

INTERACTIONS WITH OTHER DRUGS

The effects of this drug will be increased by:

- antihistamines
- sleep aids
- certain cold and cough medicines
- other tranquilizers
- antidepressants
- narcotics

(Any of the above may increase drowsiness, muscle relaxation and coordination problems.)

Before taking Diazepam or any other of the drugs listed above, the doctor should be consulted.

fold

COMMON SIDE EFFECTS

- fatigue
- drowsiness
- muscle coordination problems

These should disappear after a few days. If they do not, the doctor should be informed.

LESS FREQUENT SIDE EFFECTS AND ADVERSE REACTIONS

The drug can cause:

- skin rash (an allergic response)
- constipation
- eye pain (possibly a sign of increased pressure inside the eyeball)
- difficulty urinating
- poor bladder control
- yellowing of the skin or eyeballs (possibly a sign of liver disorder)
- faintness and dizziness (possibly a sign of blood pressure being too low)
- great excitement, anxiety and inability to sleep (called a paradoxical reaction because it is the opposite of what would be expected)

If any of these occur, tell the doctor immediately.

DOSAGE

Normal Adult Dose	2-10 mg. two to four times a day
Children's Dose	1-2½ mg. two to four times a day

- the elderly may require less of the drug, because they are more sensitive to its effects.
- children should be started at the lowest possible dose, because they are also more sensitive to its effects.

Actual size (trimmed and folded): 3-15/16" x 10-7/16"